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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GALITSKY, NIKOLAI M

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/611,527

Applicant(s)

WILLIAMS ET AL.

Examiner

Nikolai M. Galitsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### *ART UNIT DESIGNATION*

The Group and/or Art Unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

### **Restriction/Election Requirement**

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-10 and 13; drawn to isolated nucleic acids and compositions containing same, classified in class 536, subclass 23.1, and class 435, subclasses 243, 320.1, and 325. If this group is elected, then the below specie election requirement is also required. If this group is elected, then the below summarized sequence election requirement is also required.
- II. Claim 11; drawn to isolated polypeptides, classified in class 530, subclasses 300 and 350. If this group is elected, then the below summarized sequence election requirement is also required. If this group is elected, then the below summarized sequence election requirement is also required.
- III. Claim 12, drawn to an antibody, classified in class 530, subclass 387.1. If this group is elected, then the below summarized sequence election requirement is also required.
- IV. Claims 14 and 15, drawn to methods of detecting genes, classified in class 435, subclass 6. If this group is elected, then the below summarized sequence election requirement is also required.

**Examination will be restricted to only the elected sequence.**

The inventions are distinct, each from the other because:

The inventions of Groups I - III are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Group I the critical feature is a nucleic acid; for Group II the critical feature is a polypeptide; and for Group III the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Group I to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together.

Additionally, polynucleotides, polypeptides, and antibody Groups have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the Groupings of I, II, III are independent and/or distinct invention types for restriction purposes.

The inventions of Groups I, II, III and IV are related as products and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the processes of Group IV can use

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the distinctly different products of Groups I and II. Groups I and II are distinctly different products since they are directed either to isolated polynucleotides (Group I) or polypeptides (Group II) acquiring a separate status in the art as shown by their distinct subject matter and/or usage and supporting the undue search burden if the two Groups were searched together. The nucleic acids of Group I are isolated, but are not isolated as being within cells as in Group IV. Also, many probe/primer etc. uses exist for Group I nucleic acids which are unavailable for such nucleic acids when in a cell as in Group IV. The isolated polynucleotides of Group I or polypeptides of Group II can be used in the distinct processes of the inventions of Group IV (method of detecting differentially expressed genes) or in the distinct method of modulation of transcription and/or translation of a nucleic acid or, alternatively, in the method of detecting a nucleic acid.

#### SPECIE ELECTION REQUIREMENT REGARDING GROUP I:

This application contains claims directed to the following patentably distinct species of the claimed invention: The practice species below are distinct from the type of the libraries. Each of the libraries are composed of a collection cDNA clones that in turn are representative of the mRNAs expressed in the indicated source and would require separate and distinct searches if searched together.

Specie A: the library provided on an array, e.g., claim 2

Specie B: the library provided in a computer readable format, e.g., claim 3;

Specie C: a generic library, which is neither on an array nor in a computer readable format.

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Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

*SEQUENCE ELECTION REQUIREMENT APPLICABLE TO ALL GROUPS*

**In addition, each Group detailed above reads on patentably distinct sequences.**

**Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect one (1) nucleic acid sequence (See M.P.E.P. § 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a specie election requirement.**

M.P.E.P. § 803.04 states:

“Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.”

It has been determined that one (1) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of one (1) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai M Galitsky, PhD whose telephone number is (703) 308-2422. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: 06.04.2002

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER